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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/534,282

04/10/2006

Robert Peter Millar

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

07/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/534,282	Applicant(s) MILLAR, ROBERT PETER	
	Examiner Padma V. Baskar	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 28-32 is/are pending in the application.
- 4a) Of the above claim(s) 17-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 28-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/09/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's response to restriction and the amendment filed on 5/6/09 is acknowledged. Applicants elected Group I, Claims 1-16, 28-29 and new claims 30-32 which read on the elected group without traverse.

Applicant states that the present claims are distinct and non-obvious over the cited art (Mathias and Herve) as claims are directed toward the retro-inverso form of the GnRH peptide (pyroGlu-His-Trp-Ser-Tyr-Gly-Leu-Arg-Pro-Gly CONH₂, abbreviated EHWSYGLRPG), not GPRLGYSWHE as stated in the restriction requirement.

It is noted that the art also discloses retro-inverso form of the GnRH peptide (pyroGlu-His-Trp-Ser-Tyr-Gly-Leu-Arg-Pro-Gly NH₂ (see column 3, lines 49-50), where compound is substituted with one or more D-amino acids (see column 2, lines 52-55 and column 3, line 49-50) in addition to GPRLGYSWHE. The examiner would like to bring applicant's attention to claim 3, which recites peptide comprises the amino acid sequence GPRLGYSWHE and does not recite the amino acid sequence is EHWSYGLRPG as stated. Therefore, the art reads on the claimed invention and thus lack of unity, established in the previous Office action is appropriate.

Status of claims

2. Claims 4 and 29 have been amended.
New Claims 30-32 have been added.
Claims 23-27 are canceled.
Claims 1-22 and 28-32 are pending.
Claims 1-16, 28-32 are under examination.
Claims 17-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group of inventions.

Information Disclosure Statement

3. The Information Disclosure Statements filed on 8/09/05 is acknowledged and a signed copy each is enclosed to this office action.

Claim objection - Rejections 35 USC § 112, second paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-16, 28-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3, 4 and 5 are confusing because the interpretation of the claim is not clear since the claim recites "D"amino acids. Are retro-inverso amino acids of GPRLGYSWHX/ GPRLGYSWHE / GPRLGYSWHEC or D isomer configuration of GPRLGYSWHX/ GPRLGYSWHE / GPRLGYSWHEC claimed?

Claims 2-5, 28-32 and 7-16 are objected because these are dependent claims of claims 1 and 6 respectively and therefore, "a peptide " and "a vaccine" are incorrect and should be "the peptide" and "the vaccine"

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 1- 3 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Mathias U.S.Patent No: 5,434,136 (published 6/18/95).

Mathias discloses a peptide SEQ.ID.NO:1 as shown in sequence listing (see under column 16) which is 100% identical to GPRLGYSWHE SEQ.ID.NO:1 of the claimed invention. The art discloses that the disclosed compound is substituted with one or more D-amino acids including Q (see column 2, lines 52-55 and column 3, line 49-50) amino acid.

US-07-965-675-1
Sequence 1, Application US/07965675
Patent No. 5434136
GENERAL INFORMATION:
APPLICANT: Mathias, John R.
TITLE OF INVENTION: TREATMENT OF MOTILITY DISORDERS WITH A
TITLE OF INVENTION: GnRH ANALOG
INFORMATION FOR SEQ ID NO: 1:
SEQUENCE CHARACTERISTICS:
LENGTH: 10 amino acids
TYPE: AMINO ACID

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US-07-965-675-1

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Query Match          100.0%;  Score 63;  DB 1;  Length 10;
Best Local Similarity 100.0%;  Pred. No. 0.00028;
Matches   10;  Conservative   0;  Mismatches   0;  Indels   0;  Gaps   0;

Qy          1  GPRLGYSWHE 10
             |||||
Db          1  GPRLGYSWHE 10
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Thus the art meets the limitations of 1-3 and 30. The art also discloses the retro-inverso form of peptide (pyroGlu-His-Trp-Ser-Tyr-Gly-Leu-Arg-Pro-Gly NH₂) (see column 3, lines 49-50), where compound is substituted with one or more D-amino acids (see column 2, lines 52-55 and column 3, line 49-50). Therefore, the art anticipated the claimed invention.

7. Claims 1- 16 and 28-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Meloen et al U.S.Patent No: 7,361, 349 (published 4/22/08).

Meloen et disclose a peptide GNRH-I comprising pGlu-His-Trp-Ser-Tyr-Gly-Leu-Arg-Pro-Gly NH₂ (see column 1, line 54) . Therefore, it reads on claims 1-3. The art discloses the peptide comprise cysteine residue at the c-terminus end (see , column 7, lines 42-52).The peptide is conjugated to another tandem peptide or a classical type GNRH (see column 5, lines 22-64 and the formula), said peptide comprises Z1 which can also Q, Gln (see column 5, lines 55-56) . Thus, it meets the limitations of claim 4, 5, 28-32. The art discloses the vaccine comprising that the peptide GNRH-I which is coupled to carrier protein and/or in immunoadjuvant known to those skilled in the art , IFA , bacterial toxins such as pertussis or cholera etc(see column 5, lines 22-64) said vaccine is used intramuscularly (see column 13, line 64) in an animal pig, which is a livestock (see column 5, lines 25-26) for immunocastration (see column 4, lines 5-48) Treating prostate cancer, etc with GNRH is also disclosed in column 1, lines 40-45. Thus the art discloses vaccine as claimed in claims 6-16. The prior art anticipated the claimed invention.

8. No claims are allowed.

9. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 156, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571) 272-0956.

Respectfully,

/Padma V Baskar/

Examiner, Art Unit 1645

/Robert B Mondesi/

Supervisory Patent Examiner, Art Unit 1645